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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,048	05/10/2001	Thomas Y. Shen	REF/SHEN/824D	5581

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	3

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,048	SHEN, THOMAS Y.	
Period for Reply	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

A93

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 May 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-29 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informality:

The use of the trademark Bakelite on page 6 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Examiner's Suggestions/Interpretations

2. Examiner notes that claims 26-29 might better depend from claim 25.

Specifically, the phosphate buffer and enzyme protector of claims 27 and 29, both of which depend on claim 24, are not mentioned until claim 25. Examiner has interpreted claims 27 and 29 to further clarify the elements of claim 25.

Claim Objections

3. Claim 17, 20, 21, and 24 are objected to because of the following informalities: chemicals such as "polyvinyl alcohol" should not be capitalized. Additionally, in claim 20, the word "gelatin" has been misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of Trademarks renders the claim indefinite because it does not indicate whether the same material made under a different Trademarked product is equally operational. Moreover, the value of the Trademark is lost to the extent that it becomes descriptive of a product rather than the identification of a source or an origin of a product.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims are rejected under 35 U.S.C. 103(a) as being obvious over Shen et al. (6,258,230 B1) in view of Pollmann et al. (5,288,636).

Shen et al. teaches a method of coating a disposable plate electrode. Shen teaches screen printing a conductive film consisting of an anode and cathode and then drying at 40-80 °C (col. 7, lines 5-6, 27, 35). Then Shen teaches printing an electric insulating layer on the conductive film leaving bare the areas for the cathode, anode, working electrode, and reference electrode, with a circle containing the working electrode and reference electrode, also left bare (col. 7, lines 10-14 and 38-45). Shen then teaches screen printing a layer of cellulose carrier and conductive mediator and drying at a temperature from 40-80 °C (col. 7, lines 20 and 56). A protection film is then coated on and around the circle area of the reaction area (col. 7, line 57). While Shen does not specifically teach the use of an adhesive on the periphery of the circular area, it is Examiner's position that since Shen's protection film is coated on and "around the circle" and that it inherently adheres to the substrate as a coating, that the protection film acts as an "adhesive" to adhere itself to the substrate. The above represents steps a.-d. of instant claim 1.

Regarding step e., which requires application of a biological active substance to the substrate, Examiner notes that Shen teaches that the advantage of his invention is the elimination of the use of bioactive substances, which reduces production cost and increases storage term. However, Shen does teach that the conventional manufacturing of a bioactive electrode strip requires that first the carrier is printed on the

substrate and then the bio-active substances and conductive mediator are printed on the carrier. Shen's invention prints the conductive mediator and carrier in one step without the need for expensive bio-active agents.

While Shen teaches that the separation of the carrier coating step from the conductive mediator/bio-active coating step is less desirable for various reasons, his teaching of conventionality is cited by Examiner. Using the teachings of Shen, one of ordinary skill in the art desiring to use bio-active substances would have been taught to do so by splitting Shen's one-step deposition of carrier and mediator into two steps with the bio-active substance being coated last, with a mediator. It would have been obvious to one of ordinary skill in the art to use the conventional bio-active substance deposition method outlined by Shen with the expectation of the loss of benefits provided by Shen, such as longer term storage and reduced cost.

Omission of an element with the consequent loss of its function would have been obvious to one of ordinary skill in the art. *In re Wilson*, 153 USPQ 740.

While Shen teaches that the use of bioactive agents is conventional he does not specifically teach application of such agents in water solution, followed by drying. Pollmann is cited for teaching an electrode plate biosensor which comprises a conductive film coating containing an anode and cathode; an insulating layer with openings for the anode, cathode, working electrode, counter electrode, and bioactive well; cellulose carrier layer; and bioactive substance (abstract; throughout). The

bioactive substance of Pollmann is applied to the reaction well in water solution and dried at 50 °C (col. 9, lines 5-10), lying within the range claimed by Applicant. Since Shen and Pollmann both teach the same layers to comprise a biosensor plate electrode, Shen teaches the use of bioactive agent in conductive mediator, and Pollmann teaches application of bioactive agent in water, followed by drying, Pollmann would have reasonably suggested the use of a water solution and drying step in the method of Shen. It would have been obvious to one of ordinary skill in the art to use the teachings of Pollmann in the method of Shen to provide Shen with a suitable method of applying the bioactive coating layer.

Regarding the requirement of "dripping" the bioactive solution, it is Examiner's position that any method of applying minute quantities of substances in solution to a small well, would have involved drop-wise addition.

Regarding claim 17, Shen teaches the use of PVC (example 1) as a substrate.

Regarding claim 18, the carrier of Shen is a slurry of microcrystalline cellulose, PEG, PVP, salt, and water (see table in Ex. 1). A slurry qualifies as a "paste" as required by Applicant. And PEG and PVP are "high molecule" polymers, as defined by the instant specification as such.

Regarding claim 19, Shen teaches an exemplary cellulose particle size of 20 μm , lying within the range claimed by Applicant, used at 21.2%, lying within the range claimed by Applicant (example 1).

Regarding claim 20, the PVP is used at 13.4%, lying within the range claimed by Applicant (ex. 1).

Regarding claims 21 and 29, Shen teaches the use of the buffer solutions, salts, and weight percentages required by Applicant (col. 7, lines 50-52; col. 8, line 55; example 4). Regarding the pH range of Shen, i.e., 7-10, Examiner notes that overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Shen's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Regarding claim 22, Shen teaches the use of H_2O , which is pure water. Examiner notes that one of ordinary skill in the art would have found it obvious that pure water, absent interfering electrical charges, would be obtained by distillation. Laboratory grade or D.I. water is distilled for purity.

Regarding claim 23, Shen teaches that enzymes are the conventional bio-active substance (col. 6, line 61).

Regarding claims 24 and 28, Shen teaches the use of potassium ferricanide at 5% as the conductive mediator which receives electrons from reaction of the enzyme and test sample to allow concentration detection (table in ex. 1 and throughout).

Shen teaches that the combined conductive mediator and bioactive enzyme substance are printed onto the substrate in the conventional process, as required by claim 25.

Regarding claims 26-27, Pollmann teaches the use of glucose oxidase as the enzyme and dextran as the enzyme stabilizer (col. 8, lines 1-25). Regarding the required concentrations, it is Examiner's position that selection of an appropriate concentration would have been determined by an ordinary artisan to optimize the results of his biosensor.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McAleer et al. and Maley et al. are cited for teaching disposable glucose and lactate test strips with various conductive electrode, insulating, carrier, and enzyme layers.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 15, 2003